



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	1081.02
True Name	Bordetella Bronchiseptica Vaccine, Avirulent Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Nobivac Intra-Trac Oral Bb - Intervet Mexico S.A. de C.V. Nobivac Intra-Trac Oral Bb - Merck Animal Health Nobivac Intra-Trac Oral Bb - No distributor specified Nobivac Oral Bb - No distributor specified
Date of Compilation Summary	April 22, 2019

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy									
Pertaining to	<i>Bordetella bronchiseptica</i>									
Study Purpose	To demonstrate efficacy against <i>Bordetella bronchiseptica</i>									
Product Administration	One dose administered by the oral route									
Study Animals	7- to 8-week-old dogs; 20 vaccinates, 20 controls									
Challenge Description	Dogs were challenged with <i>B. bronchiseptica</i> 21 days post vaccination.									
Interval observed after challenge	Clinical signs were observed daily for 28 days post challenge.									
Results	<p>Primary outcome variable was coughing. An affected dog was defined as having spontaneous coughing or spontaneous coughing with retching on 2 or more consecutive days.</p> <table border="1"> <thead> <tr> <th>Treatment Group</th> <th># of Animals</th> <th># of Animals Affected</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>20</td> <td>12</td> </tr> <tr> <td>Controls</td> <td>20</td> <td>20</td> </tr> </tbody> </table> <p>Raw data shown on attached pages.</p>	Treatment Group	# of Animals	# of Animals Affected	Vaccinates	20	12	Controls	20	20
Treatment Group	# of Animals	# of Animals Affected								
Vaccinates	20	12								
Controls	20	20								
USDA Approval Date	February 16, 2016									

Clinical Observations Post Challenge

Treatment Group	Dog ID	Day 0*	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9
A (Vaccinates)	ABG-5	-	-	-	-	-	-	-	-	-	-
	ACH-5	-	-	-	-	-	-	-	-	-	-
	WSG-5	-	-	-	-	-	-	-	-	-	-
	XBG-5	-	-	-	CR	-	CS	-	CS	CR	CR
	XEG-5	-	-	-	-	-	-	-	-	-	-
	YQH-5	-	-	-	-	-	-	-	-	-	-
	YTF-5	-	-	-	-	-	-	-	-	-	-
	YVE-5	-	-	-	-	-	CS	-	-	CS	-
	YYH-5	-	-	-	CS	-	-	CR	CS	CS	CS
	YZH-5	-	-	-	-	-	CR	-	CS	CS	-
	ZEG-5	-	-	-	-	-	-	-	-	-	-
	ZFG-5	-	-	-	-	-	-	-	-	-	-
	ZGG-5	-	-	-	-	-	-	-	-	-	-
	ZJH-5	-	-	-	-	-	-	-	-	-	-
	ZLG-5	-	-	-	-	-	-	-	-	-	CS
	ZQG-5	-	-	-	-	-	-	-	-	-	-
	ZSH-5	-	-	-	-	-	-	-	-	-	-
	ZVG-5	-	-	-	-	-	-	-	CR	-	-
	ZWH-5	-	-	-	-	-	-	-	-	-	-
	ZXG-5	-	-	-	-	-	-	-	CS	CS	CR
B (Controls)	AAG-5	-	-	-	-	-	-	-	-	-	-
	ADH-5	-	-	-	-	-	-	-	CR	-	-
	WTG-5	-	-	-	-	-	D	CR	CR	Euthanized Day 27	
	XAG-5	-	-	-	-	CS	-	-	-	-	-
	XCH-5	-	-	-	CS	-	-	-	-	-	-
	YPH-5	-	-	-	-	CR	CS	CR	CR	CR	CS
	YUF-5	-	-	-	-	-	-	-	-	-	-
	YWE-5	-	-	-	-	-	-	-	-	-	-
	ZAH-5	-	-	-	-	-	CS	CS	CR	CR	CR
	ZBG-5	-	-	-	CS	-	-	CR	CS	CR	CR
	ZCH-5	-	-	-	-	-	-	-	-	-	-
	ZDH-5	-	-	-	-	-	-	-	CS	CS	CS
	ZHH-5	-	-	-	-	-	-	-	-	CR	CR
	ZKH-5	-	-	-	-	-	-	-	CS	-	CR
	ZOG-5	-	-	-	-	-	-	-	CR	-	CR
	ZPH-5	-	-	-	-	-	-	-	-	-	-
	ZRH-5	-	-	-	-	-	-	CS	-	CS	-
	ZTH-5	-	-	-	-	-	-	-	-	CS	CS
ZUG-5	-	-	-	-	-	-	-	-	-	CS	CR
ZZG-5	-	-	-	-	-	-	CS	-	-	-	-

*Challenge Day

(-) = No clinical observations; CS=Spontaneous Cough; CR=Spontaneous Cough with Retching; D=Depressed

Clinical Observations Post Challenge – continued

Treatment Group	Dog ID	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15	Day 16	Day 17	Day 18	Day 19	
A (Vaccinates)	ABG-5	-	-	-	-	-	-	-	-	-	CS	
	ACH-5	-	-	-	-	-	-	-	-	-	-	
	WSG-5	-	-	-	-	-	-	CR	CR	-	-	
	XBG-5	CR	CS	CR	CR	CS	CR	CS	-	-	-	
	XEG-5	-	-	-	-	-	-	-	-	-	-	
	YQH-5	-	-	-	-	-	-	-	CS	-	CR	
	YTF-5	-	-	-	-	-	-	-	-	-	-	
	YVE-5	CS	-	CR	CS	CR	CR	CR	CS	-	CR	
	YYH-5	CS	-	CR	CS	CS	CR	CS	CS	CR	CR	
	YZH-5	CR	CR	-	CR	CS	-	CR	CS	CR	CR	
	ZEG-5	CS	-	-	-	-	-	-	-	-	CS	
	ZFG-5	-	-	-	-	-	CS	Euthanized on day 36				
	ZGG-5	-	-	-	-	-	-	-	-	-	-	
	ZJH-5	-	-	CS	-	-	-	-	-	-	CS	
	ZLG-5	-	-	-	-	-	CS	-	CS	CR	-	
	ZQG-5	-	-	-	-	-	-	-	-	-	-	
	ZSH-5	-	-	-	-	-	-	-	-	-	-	
	ZVG-5	-	-	-	-	-	CR	CR	CR	-	CR	
	ZWH-5	-	-	-	-	CR	CR	CR	CR	CR	CR	
	ZXG-5	-	-	CS	CR	CR	CR	CR	CR	CR	CR	
B (Controls)	AAG-5	-	-	-	CR	CS	CR	-	-	-	CR	
	ADH-5	-	CR	-	-	-	CR	-	-	CS	CR	
	WTG-5	Euthanized on day 27										
	XAG-5	-	-	-	-	CR	-	CS	CR	CS	CR	
	XCH-5	-	-	-	-	CS	-	-	-	CR	CS	
	YPH-5	CS	CS	CR	CS	CR	CS	CR	CR	CR	CR	
	YUF-5	-	CS	-	-	CR	CR	CR	-	-	-	
	YWE-5	-	-	-	-	CR	CS	CS	-	CS	-	
	ZAH-5	CS	-	CR	CR	CR	CR	-	CS	CS	CR	
	ZBG-5	CR	CR	CR	CR	CR	CR	CS	CR	CR	CR	
	ZCH-5	-	CR	-	CS	CS	-	-	-	CS	CS	
	ZDH-5	CS	CS	CS	CR	CS	CR	CS	CS	CS	CS	
	ZHH-5	-	CS	CR	-	CS	-	CS	CR	CS	CR	
	ZKH-5	CS	CR	-	-	CS	-	-	-	CR	-	
	ZOG-5	-	CS	CS	CS	CS	CR	-	-	CS	CR	
	ZPH-5	CR	-	-	-	CR	CR	CS	CS	-	CR	
	ZRH-5	-	-	CS	-	CR	-	CS	-	CR	CS	
	ZTH-5	CR	-	CS	CS	CS	CR	CS	CR	-	CS	
	ZUG-5	CR	CS	CR	CR	CS	CR	CR	-	-	CS	
	ZZG-5	-	-	-	CS	CS	CS	Euthanized on day 36				

(-) = No clinical observations; CS=Spontaneous Cough; CR=Spontaneous Cough with Retching

Clinical Observations Post Challenge – continued

Treatment Group	Dog ID	Day 20	Day 21	Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28	
A (Vaccinates)	ABG-5	CS	CS	-	-	-	CR	CR	CR	-	
	ACH-5	-	-	-	CS	-	-	-	-	-	
	WSG-5	-	-	-	-	-	CR	-	-	-	
	XBG-5	-	CS	CR	-	-	-	-	CS	-	
	XEG-5	-	-	-	-	-	-	-	-	-	
	YQH-5	CR	-	-	-	CS	CR	CS	-	-	
	YTF-5	-	-	-	CS	-	-	-	-	-	
	YVE-5	CR	-	CR	CR	CS	CS	CR	CS	CS	
	YYH-5	CR	CS	CR	CS	-	-	-	CR	CR	
	YZH-5	-	CR	CR	CR	CR	CR	CS	-	-	
	ZEG-5	CR	-	-	CS	-	-	-	CS	-	
	ZFG-5	Euthanized on day 36									
	ZGG-5	-	-	-	-	-	-	-	-	-	-
	ZJH-5	-	-	-	-	-	-	-	-	-	-
	ZLG-5	-	-	-	CS	-	-	-	-	-	-
	ZQG-5	-	-	-	-	-	-	-	-	-	-
	ZSH-5	-	-	-	-	-	-	-	-	-	-
	ZVG-5	CR	CR	-	-	CR	-	-	-	-	CR
	ZWH-5	-	-	-	-	-	-	-	-	-	-
	ZXG-5	CR	CR	CR	CR	CS	-	-	CS	CR	
B (Controls)	AAG-5	CS	CS	CR	CR	CR	-	CR	CR	CR	
	ADH-5	CR	-	CR	-	-	CR	CR	CS	CR	
	WTG-5	Euthanized on day 37									
	XAG-5	CR	CS	CR	CS	CR	CS	CS	-	CS	
	XCH-5	-	-	CS	CS	CR	-	-	-	-	
	YPH-5	CS	CS	CS	CS	CS	CR	CR	CR	CS	
	YUF-5	-	-	-	-	-	-	CR	-	-	
	YWE-5	CR	-	CR	-	-	CS	-	-	-	
	ZAH-5	CR	CS	CS	CR	-	-	CS	CR	CS	
	ZBG-5	CR	CR	CR	CR	CR	CS	CR	CR	CR	
	ZCH-5	-	-	-	CS	-	-	-	-	CR	
	ZDH-5	-	CS	CS	CS	CS	CS	-	CS	CS	
	ZHH-5	-	CR	CR	-	CS	-	CS	CS	CR	
	ZKH-5	-	CR	CR	-	-	-	-	CR	-	
	ZOG-5	CR	CR	-	-	CS	-	CS	-	CS	
	ZPH-5	CR	CR	CS	CS	CS	-	CR	CS	CS	
	ZRH-5	CR	-	CS	CS	CS	CR	CS	CR	CR	
	ZTH-5	CS	CR	-	CS	CS	CS	CS	CS	-	
	ZUG-5	CS	CR	CR	CR	CS	-	CR	CS	CS	
	ZZG-5	Euthanized on day 36									

(-) = No clinical observations; CS=Spontaneous Cough; CR=Spontaneous Cough with Retching

Study Type	Safety								
Pertaining to	ALL								
Study Purpose	To demonstrate safety under field conditions								
Product Administration	One dose administered by oral route								
Study Animals	330 dogs represented four different geographic locations; 110 dogs were 7-8 weeks of age, which is the recommended minimum age, 220 dogs ranged in age from 8 weeks to 17 years.								
Challenge Description	NA								
Interval observed after vaccination	Dogs were observed immediately after vaccination for adverse events. Client-owned dogs were monitored by the owners for 14 days (\pm 3 days) following vaccination after which the dogs received a final physical exam. Purpose-bred dogs were observed daily for adverse events for 14 days following vaccination and buccal cavities were observed on days 3, 7, and 14 post vaccination.								
Results	<p>There were no immediate post vaccination reactions related to the administration of the product.</p> <p><u>Summary of adverse events</u></p> <table border="1"> <tr> <td>No adverse event observed</td> <td>314 dogs</td> </tr> <tr> <td>Adverse event observed</td> <td>16 dogs/17 events</td> </tr> <tr> <td> Deemed unrelated to product</td> <td>10 events</td> </tr> <tr> <td> Cause unknown</td> <td>7 events</td> </tr> </table> <p>Raw data: see attached.</p>	No adverse event observed	314 dogs	Adverse event observed	16 dogs/17 events	Deemed unrelated to product	10 events	Cause unknown	7 events
No adverse event observed	314 dogs								
Adverse event observed	16 dogs/17 events								
Deemed unrelated to product	10 events								
Cause unknown	7 events								
USDA Approval Date	July 6, 2016								

Adverse Events Following Vaccination

Dog ID	Site	Serial	Date of Vaccination	Start Date of Adverse Event	Description of Adverse Event	Serious / Non-Serious	Associated with Test Vaccine
SIF010	02	02	06JAN2016	20JAN2016	Pinnal irritation; treated	Non-Serious	Unknown
BAK009	03	02	14DEC2015	29DEC2015	Murmur; no treatment	Non-Serious	Not Related
BAK011	03	01	14DEC2015	18DEC2015	Retching; no treatment	Non-Serious	Unknown
BAK013	03	02	14DEC2015	27DEC2015	Epileptic seizure; no treatment	Non-Serious	Not Related
BAK015	03	01	14DEC2015	16DEC2015	Urinary tract disorder NOS; treated	Non-Serious	Not Related
BAK017	03	02	14DEC2015	28DEC2015	Pinnal irritation; no treatment	Non-Serious	Not Related
BAK038	03	01	14DEC2015	14DEC2015	Muscle tremor; no treatment	Non-Serious	Unknown
BAK046	03	01	18DEC2015	18DEC2015	Cough; no treatment	Non-Serious	Not Related
BAK050	03	01	28DEC2015	08JAN2016	Dermal cyst(s); treated	Non-Serious	Not Related
BAK051	03	02	28DEC2015	28DEC2015	Emesis; no treatment	Non-Serious	Unknown
BAK054	03	02	28DEC2015	12JAN2016	Murmur; no treatment	Non-Serious	Unknown
BAK066	03	02	28DEC2015	10JAN2016	Gastroenteritis; treated	Non-Serious	Not Related
BAK094	03	02	13JAN2016	26JAN2016	Corneal ulcer; treated	Non-Serious	Not Related
BAK103	03	02	14JAN2016	26JAN2016	Diarrhea; no treatment	Non-Serious	Not Related
BAK111	03	02	19JAN2016	29JAN2016	Otitis externa; treated	Non-Serious	Not Related
BAK111	03	02	19JAN2016	29JAN2016	Lymphadenitis; treated	Non-Serious	Unknown
108015	04	02	08DEC2015	11DEC2015	Allergic edema (facial swelling); no treatment. Mild swelling of upper and lower eyelids bilaterally and mild swelling of muzzle	Non-Serious	Unknown